

## **REMARKS**

This responds to the non-final Office Action mailed August 23, 2005. The Examiner has applied new grounds of rejection to claims 44-47 and 60-67 and, in light of the new grounds of rejection, has not made this action final. By way of the present amendment, claim 44 has been amended, claims 45- 47 have been canceled, and claims 68-70 have been added. With respect to claim 44, the subject matter previously found in dependent claim 45 has been added to claim 44. With respect new independent claim 68, this claim has been patterned after original claim 44, but adding that the device is for use in an annuloplasty procedure "on a mitral valve having an annulus" and further adding "a plurality of coupling devices configured to attach the collapsible member to the annulus within the left ventricle." For at least the reasons provided below, Applicants respectfully submit that this application is in complete condition for allowance.

### **The Rejection of Claims 44-47 under 35 U.S.C. § 102(e)**

The Examiner rejected claims 44-47 under 35 U.S.C. § 102(e) as allegedly being anticipated by Solem, U.S. Patent No. 6,210,432 (the Solem '432 patent). In this regard, and with respect to these four claims, the Examiner only stated:

Solem discloses in figures 2 and 7 an implantable annuloplasty device comprising a collapsible member 9, mesh 11, and coupler 10 capable of implantation through a catheter.

As noted above, independent claim 44 has now been amended to include the subject matter previously found in dependent claim 45. Thus, claim 44 now recites a "mesh covering, the mesh covering extending over at least a portion of the collapsible member."

The Examiner refers to "cover sheet 11" disclosed in the Solem '432 patent as a "mesh." However, the Solem '432 patent completely fails to disclose a "mesh" and, instead, simply states that the cover sheet 11 is composed of "synthetic material" (col. 4, lines 14-16). Moreover, the clear purpose of the cover sheet 11 is to allow the device to be directed through the venous system of a patient without snagging of the hooks 10, which are ultimately adapted to engage and penetrate into the walls of the coronary sinus 5. If the cover sheet 11 was formed from a mesh (which is mere speculation) snagging would likely occur between the cover sheet 11 and the hooks 10 as the cover sheet 11 is retracted to expose the elongate body 8 within the coronary sinus 5, as set forth in lines 21-22 of column 4 of the Solem '432 patent.

On the other hand, the mesh element used in Applicants' invention is meant to remain implanted so as to, for example, allow for tissue ingrowth. There is no reason or suggestion provided for using a mesh material for constructing the cover sheet 11 disclosed in the Solem '432 patent. In fact, the cover sheet 11 is not meant to be implanted with the elongate body 8 but merely provides a temporary covering during the delivery of elongate body 8. Clearly, one of ordinary skill in the art would choose a smooth synthetic material which is not susceptible to snagging during the retraction process to expose the hooks 10 as set forth by Solem. For these reasons, the Solem '432 patent fails to anticipate the invention set forth in independent claim 44 and, furthermore, no motivation exists, absent improper hindsight, to modify the cover sheet 11 such that it is formed from a mesh material. The rejection of claim 44 over the Solem '432 patent should therefore be withdrawn. Claims 45-47 have been canceled and, therefore, the rejection of these claims is moot.

### **The Rejection of Claims 44, 46 and 60-67 under 35 U.S.C. § 102(e)**

The Examiner has rejected these claims as allegedly being anticipated by St. Goar et al., U.S. Patent No. 6,629,534 (the St. Goar '534 patent). In this regard, and with respect to these ten claims, the Examiner only states:

St Goar discloses in figure 81 and columns 39-40 an implantable annuloplasty device comprising a collapsible member 9 or plicating fasteners connected by tensioning element that cinches the fasteners and is locked by tying.

The rejection of claim 44 is now moot as the subject matter of dependent claim 45 has been added to claim 44 and dependent claim 45 was not rejected on the basis of the St. Goar '534 patent. The rejection of dependent claim 46 is moot due to the cancellation of this claim.

With regard to Fig. 81, which is relied upon by the Examiner as anticipating independent claim 60, claim 60 requires:

an elongate tensioning element coupled with the plurality of non-plicating fasteners and configured to be tensioned by pulling on only one end thereof to place the plurality of non-plicating fasteners in an activated state positioned closer together to plicate the tissue between the fasteners (underlining added).

The entire written disclosure directed to the embodiment shown in Fig. 81 of the St. Goar '534 patent is contained in the first full paragraph of column 40 as follows:

As an alternative to placement of discrete annuloplasty rings, the valve annulus can be reinforced and tightened by placing a plurality of anchors, such as staples 540 about the annulus of the mitral valve, as shown in Fig. 81. A suture 542 or other filament can then be placed through the anchors 540 and tightened in a "purse string" fashion. The suture filament can then be tied off to maintain the desired tightened and enforcement of the valve annulus.

First, there is no enablement or teaching as to how one of ordinary skill would use a catheter to thread a suture through the plurality of anchors 540 after they have been secured about the annulus as schematically shown in Fig. 81. Thus, the reference fails to be effective prior art from that standpoint. Second, it is clear that the suture 542 is a loop structure as two portions of the suture are extending into the catheter device at the location of the lead line for reference numeral 542. Thus, both ends of the suture must be pulled in order to tighten the anchors 540 in the disclosed "purse string" fashion. Claim 60, and Applicants' supporting disclosure clearly require that the elongate tensioning element be tensioned "by pulling on only one end thereof to place the plurality of non-plicating fasteners in an activated state positioned closer together to plicate the tissue between the fasteners." Thus, not only is there no enablement or teaching as to how one of ordinary skill in the art would carry out the method that is ostensibly shown in Fig. 81 of St. Goar '534, there is clearly no disclosure or teaching with regard to an elongate tensioning element that is coupled with a plurality of non-plicating fasteners such that only one end thereof needs to be pulled in order to plicate the valve tissue. For at least these reasons, independent claim 60 fails to be anticipated by the St. Goar '534 patent and the rejection of claims 60-67 should therefore be withdrawn.

#### **New Claims 68-70**

New claim 68 has been added, as noted above, and is also respectfully submitted to be allowable over the art of record. Notably, with respect to the Solem '432 patent, the device disclosed in that patent is specifically and only configured to be attached within the coronary sinus of a patient, and not within the left ventricle of the heart as with the present invention, as set forth in claim 68. Thus, not only does the

device shown in the Solem '432 patent fail to teach a collapsible member in an extended position "for insertion into a left ventricle," it clearly fails to provide a "plurality of coupling devices configured to attach the collapsible member to the annulus within the left ventricle" (underlining added). Instead, the hooks 10 taught in the Solem '432 patent are specifically and only configured to engage venous tissue within the coronary sinus upon activation. Such coupling devices would not be capable of attaching the collapsible member of Solem '432 to the annulus within the left ventricle as set forth in claim 68.

With regard to the St. Goar '534 patent, this patent fails to disclose or suggest the combination of a "collapsible member," "a shortening device," and "a plurality of coupling devices" as set forth in new claim 68. Instead, at most, the St. Goar '534 patent discloses a suture threaded through a plurality of fasteners or coupling devices. There is, at least, no separate "collapsible member" taught or suggested in the St. Goar '534 patent. Thus, independent claim 68 is also patentable over the St. Goar '534 patent.

Dependent claims 69 and 70 respectively depend from independent claims 60 and 68 and are respectfully submitted to be in condition for allowance for at least the same reasons as the corresponding independent claims.

The application is now believed to be in complete condition for allowance. If the Examiner believes any matter requires further discussion, the Examiner is respectfully invited to telephone the undersigned attorney so that the matter may be promptly resolved.

Applicants do not believe any other fees are due in connection with filing this response other than the extension fee. However, if any fees are necessary, the

Commissioner is hereby authorized to charge any underpayment or fees associated with this communication or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,

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